510(k) Summary

K080953

As Required by 21 section 807.92 (c)

FEB 20 2009

1- Submitter Name: Genexel-Sein, Inc (formerly Sein Electronics Co., Ltd)
2- Address: 111 Yangjae-Dong, Seocho-Gu, Seoul, Korea
3- Phone: 82 2 575 1141
4- Fax: 82 2 575 1668
5- Contact Person: Won Ky Kim, Director of R&D
6- Date summary prepared: November 20, 2008
7- Official Correspondent: Mansour Consulting LLC
8- Address: 845 Aronson Lake Court. Roswell, GA 30075 USA
9- Phone: 678-908-8180
10- Fax: 678-623-3765
11- Contact Person: Jay Mansour, President
12- Device Trade or Proprietary Name: BLOOD GLUCOSE AND BLOOD PRESSURE MONITOR SYSTEM, MODEL DUO-CARE
13- Device Common or usual name: Blood Glucose Monitor, Blood glucose test strips, quality control material, and Blood Pressure Monitor
14- Device Classification Name:
System, test, blood glucose, over the counter
Glucose oxidase, glucose
Single (specified) analyte controls
System, measurement, blood-pressure, non-invasive
15- Substantial Equivalency is claimed against 510K #K052108

16- Description of the Device:

DUO-CARE Genexel-Sein Blood Glucose & Pressure Monitor system combines the function of a blood glucose monitoring system and a blood pressure meter in one unit. Supplies with the meter are test strips, lancets, lancing device, storage case and control solution. The blood glucose monitoring system is turned on by strip insertion; Once the user confirms that the numerical code on the display, and strip bottle all match, a test strip is inserted into the meter and glucose testing can proceed. The user then supplies finger-tip or control solution to the strip and the meter starts the measurement, which is completed in 5 seconds. Genexel-Sein, Inc has provided instructions and illustrations explaining, that the blood drop will be pulled into the strip sample entry by capillary action until meter beeps and the result will be show on liquid crystal display ("LCD") after 5 seconds. Results are automatically stored in the meter's memory for tracking purposes. The capacity of memory is 150 blood glucose values and average value of past 14 days or 30 days. Control Solution is sold separately from the kit.

DUO-CARE adopts the wrist type cuff for blood pressure meter part. The cuff and control unit are combined into a single wrist-mounted assembly. The user interface panel has power switch, mode switch, memory switch, for blood pressure meter part and LCD for displaying the systolic blood pressure, diastolic blood pressure, pulse rate, date and time. This device has the memory function that permits memory and display of the 60 most recent measurement results.

User should wrap the pressure cuff around the wrist with the palm facing up and pushes the "Power" button. The cuff will be full with appropriate air pressure automatically. Pressurization is automatically governed. If the initial inflation pressure (180mmHg) is inadequate for measurement, i.e. lower that the patient's systolic pressure, the pump will automatically re-pressurize to a preset level (30 mmHg) above the initial level. Symbols in the LCD indicate pressurization status at all times. The air of cuff is automatically deflated during blood pressure measurement. No special training beyond basic ability to follow instruction is required. Since the products are designed for home use, detailed instructions on avoidance of practices that adversely affect the accuracy of measurements are included in the instruction manual.

ATTACHMENT 11

17- Intended use of the device: (refer to FDA form attached)

The DUO-CARE blood glucose and blood pressure measurement system consists of a meter with wrist cuff and test strips. The system is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes mellitus, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates.
Also the system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and the oscillometric method of measurement.
The system includes optional accessory software that is installed on the users' computers for data management purposes.

18- Safety and Effectiveness of the device:

This device is safe and effective as the predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14- Summary comparing technological characteristics with predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SUBSTANTIALLY EQUIVALENT** to the predicate device. Refer to the explanations/details within the main submission.

FDA file reference number	510k # K052108
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	IDENTICAL
Target population	
Design	
Materials	
Performance	
Sterility	
Biocompatibility	
Mechanical safety	
Chemical safety	
Anatomical sites	
Human factors	VERY SIMILAR (USB CABLE ADDED TO TRANSMIT MEASURED DATA TO PC, SOFTWARE ADDED AT PC SIDE)
Energy used and/or delivered	IDENTICAL
Compatibility with environment and other devices	
Where used	
Standards met	
Electrical safety	
Thermal safety	
Radiation safety	

Refer to the submission for more details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Genexel-Sein, Inc.
c/o Jay Mansour
Mansour Consulting, LLC
845 Aronson Lake Court
Roswell, GA 30075

FEB 20 2009

Re: k080853
Trade/Device Name: DUO-CARE
Regulation Number: 21CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX, DXN
Dated: February 3, 2009
Received: February 12, 2009

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K080853

Device Name: DUO-CARE

Indication For Use:

The DUO-CARE blood glucose and blood pressure measurement system consists of a meter with wrist cuff and test strips. The system is intended for use in the quantitative measurement of glucose in whole blood taken from the fingertip. Testing is done outside the body (In Vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by persons with diabetes mellitus, or in clinical settings by healthcare professionals, as an aid to monitor the effectiveness of diabetes control. It is not intended for use on neonates.
Also the system measures systolic and diastolic blood pressure and pulse rate from adult's wrist in the home care environment. The device employs a wrist cuff and the oscillometric method of measurement.
The system includes optional accessory software that is installed on the users' computers for data management purposes.

Prescription Use √ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use √ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Ruth Chesler For Courtney Harper

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080853

ATTACHMENT 10